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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,319	08/18/2000	Michael R. Slater	PRMG-04578	7302

23535 7590 10/25/2004

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/641,319

Applicant(s)

SLATER ET AL.

Examiner

Richard G. Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30, 40, 44, 48 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30, 40, 44, 48 is/are rejected.
- 7) ☒ Claim(s) 49 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/9/2004 has been entered.

Applicants amendment of claims 22 and 23, the cancellation of claim 41 and the addition of new claims 48 and 49, in the paper of 8/9/2004, is acknowledged. Claims 22-30, 40, 44, 48 and 49 are at issue and are present for examination.

Applicants' arguments filed on 8/9/2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Specification

The disclosure is objected to because of the following informalities:

Applicants traversal of the previous objection to the specification for the "sequences" found on page 36, line 21-22 is persuasive, and thus no sequence identifier is necessary for these "3 or less amino acid sequences".

Claim Objections

Claim 49 is objected to because of the following informalities:

Claim 49 is dependent on rejected claim 40.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 22-30, 40 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office actions as it applied to previous claims 22-30, 40 and 44. In response, applicants have made a minor amendment to claims 22 and 23 and argue the rejection as it applies to the newly amended claims. Newly added claims 48 and 49 are included in the rejection for the reasons previously stated for claims 22-30, 40 and 44.

Applicants in their traversal initially note that the present claims are copied from U.S. Pat. No. 5,939,301 (the "301" patent) and that the present specification provides substantially more support for the claims than does the 301 patent, which the office has taken the position was sufficient to support its issued claims. It is acknowledged that in

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the previous response to this rejection applicants made this same assertion with respect to U.S. Pat. No. 5,948,614.

Applicants submit that the specification of the present invention provides detailed guidance demonstrating that the inventors were in possession of the claimed invention as highlighted in applicants previous response, applicants assert that the present specification provides detail of the structure/function relationship between the structure of the polymerase and its enzymatic activities, in line with the Revised Interim Written Description Guidelines. Applicants submit that these include 1) Numerous illustrative examples of specific non-naturally occurring Tne DNA polymerases; 2) Substantial guidance for the selection of numerous addition non-natural *Thermotoga neapolitana* DNA polymerases based on homologies to other characterized polymerases and 3) Identification of specific zones that can be mutated to yield enzymes with the desired activities and properties.

Applicants further submit that the examiner has not provided evidence to support the position that Applicants guidance is insufficient to support the claim scope, but merely arguments and unsupported conclusory statements. Applicants further note that the Erlich reference used in the 103 rejection, is so used in a manner that directly contradicts the Examiner's position in the written description rejection (citing Erlich for the proposition that with the *Thermotoga neapolitana* DNA polymerase sequence and prior art knowledge, a variety of variant sequences are readily knowable). Thus applicants submit that the only evidence cited relevant to the written description issue supports the allowability of the claims.

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Applicants further submit that the written description guidelines provide numerous biotechnology examples to highlight allowable and non-allowable subject matter and that these guidelines support applicants position. Applicants submit that the full structure is provided and the regions of the structure that relate to the various activities of the enzymes are described.

Applicants argument in full is acknowledged, however, not found persuasive for the following reasons. First applicants are again reminded that the currently claimed genus remains large and variable with potentiality of comprising many different DNA polymerase type-I mutants many of which have not yet been identified. This genus encompasses any and all mutants of any pol-I type DNA polymerase or fragments thereof capable of DNA synthetic activity which is derived from *Thermotoga neapolitana*.

While admittedly, applicants do teach examples of some specific non-naturally occurring The DNA polymerases, as well as the domains associated with the different enzymatic activities of The pol-I type DNA polymerase, this guidance remains insufficient to adequately describe the currently claimed genus which encompasses all compositions comprising any non-naturally occurring pol-I type DNA polymerases, or fragments thereof wherein said polymerase is derived from *Thermotoga neapolitana*. The claimed genus includes any The pol-I type DNA polymerase, fragment thereof, mutant or variant thereof.

In response to applicants submission that the examiner has not provided evidence to support applicants position that applicants have not adequately described

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the claimed genus, applicants submission is somewhat unclear as to what type of evidence applicants are referring to. It is unclear what type of evidence would support what applicants have not described. To the contrary it is believed that applicants should provide evidence as to what **is** adequately described.

Finally, applicants reference to the written description guidelines is acknowledged and these guidelines have been reviewed in the process of maintaining the current rejection. Applicants submission that applicants disclosure provides more support than the allowable subject matter of Example 14 is acknowledged, however, applicants are reminded that the referred to Example is merely an example for training purposes, and that based on what is presented in the example, that is the structure of the claimed protein (i.e. SEQ ID NO: 3 and those molecules having at least 95% sequence identity to SEQ ID NO: 3) and the function of the claimed protein (able to catalyze the reaction of A to B), it has been determined that the claimed genus is not adequately described. While applicants claimed genus is similarly defined with respect to function (i.e. capable of DNA synthetic activity), applicants have not structurally defined the claimed genus in a similar fashion.

The claimed genus is infinitesimally large compared to that which applicants have shown possession of.

Given this lack of additional representative species as encompassed by the above claims, applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize applicants were in possession of the claimed invention.

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Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 22 and 23 remain rejected under 35 U.S.C. 102(e) as being anticipated by Chatterjee et al. (U.S. Patent No: 5,912,155).

The rejection was stated in the previous office action. In response to this rejection applicants have amended claims 22 and 23 and traverse the rejection as it applies to newly amended claims 22 and 23.

Applicants traversal of this rejection is based on applicants submission of a statement under CFR 1.608(b) with supporting declarations demonstrating that Applicant is *prima facie* entitled to a judgement relative to the patentee. The submission of the above declaration under CFR 1.608(b) with supporting declarations is not persuasive to overcome the present rejection at this time because as noted in the MPEP, Section 2308, regarding filing of a declaration under 1.608 (b) "...the evaluation

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of a showing under 37 CFR 1.608(b) is made by an administrative patent judge".

However, an interference cannot be declared unless the common invention is

patentable to the applicant. *Hilborn v. Dann*, 546 F.2d 401, 192 USPQ 132 (CCPA

1976). These claims are not patentable to the applicant because they fail to comply

with the written description requirements of 35 USC 112.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22, 23, 25, 27-30, 44 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chatterjee et al. (U.S. Patent No: 5,912,155) as applied to claims 22, and 23 above, and further in view of Erlich et al.(Science 252:1643-1651, June 1991).

The rejection was stated in the previous office action as it applied to claims 22-30, 40 and 44. In response to this rejection applicants have amended claims 22 and 23 and traverse the rejection as it applies to the newly amended claims. Newly added claim 48 is included in the rejection for the reasons previously stated for claims 22-30, 40 and 44.

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Applicants traverse this rejection on the basis that Chatterjee only provides a very limited and partial sequence of the *Thermotoga neapolitana* polymerase, therefore Chatterjee in combination with any other polymerase reference, cannot provide an expectation of success that mutants can be generated that maintain or remove the desired activities. Applicants further submit that Chatterjee guesses wrong that particular mutants might be made, based on the instant applications own teaching that deleting the 3'-5' domain of *Thermotoga neapolitana* destroys polymerase activity as seen in data related to instantly described pJM284DeltaB.

Based on applicants above traversal the rejection of claims 24, 26 and 40 have been withdrawn from this rejection, however as applicants traversal does not address the inventions of claims 22, 23, 25, 27-30, 44 and 48, the claims remain rejected for the reasons previously stated.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a stylized flourish extending from the end.

Richard G Hutson, Ph.D.
Primary Examiner
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rg
10/20/2004